UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/531,315	04/13/2005	Yuki Katayama	00005.001258.	6439

5514 7590 06/24/2009

FITZPATRICK CELLA HARPER & SCINTO
30 ROCKEFELLER PLAZA
NEW YORK, NY 10112

EXAMINER	
HOBBS, LISA JOE	

ART UNIT	PAPER NUMBER
1657	

MAIL DATE	DELIVERY MODE
06/24/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/531,315	KATAYAMA ET AL.	
	Examiner	Art Unit	
	Lisa J. Hobbs	1657	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 April 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3,38,39 and 41-50* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3,38,39 and 41-50* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 04 February 2009 has been entered.

Priority

Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Should applicant desire to obtain the benefit of foreign priority under 35 U.S.C. 119(a)-(d) prior to declaration of an interference, a certified English translation of the foreign application must be submitted in reply to this action. 37 CFR 41.154(b) and 41.202(e).

Failure to provide a certified translation may result in no benefit being accorded for the non-English application.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claim1-3, 38-39, 41-50 are rejected under 35 U.S.C. 103(a) as being unpatentable over Takayuki et al. (JP 09 285298 A), Hama et al. (WO 97/40376), and Miyauchi et al. (US 5736406 A) in view of Miki et al (US 6162607 A).

Takayuki et al teach a method of measuring HDL-cholesterol in a specimen such as serum or plasma by treating the specimen with a cholesterol esterase and cholesterol oxidase in the presence of albumin separately derived from the specimen. Takayuki et al teach that the specimen is treated with a polyanion such as a sulfated polysaccharide, particularly dextran sulfate, as well as with a nonionic surfactant. Takayuki et al teach that by using peroxidase and a suitably oxidizable color fixative, the amount of hydrogen peroxide generated can be determined.

In addition, Takayuki et al teach that cholesterol dehydrogenase may also be used with cholesterol esterase in combination with a coenzyme so as to use well-known methods of detecting reduced enzymes. Furthermore, Takayuki et al teach that PEG, or polyethylene glycol, is used as a nonionic surfactant in the methods of Takayuki et al, although any well-known nonionic surfactants may be used, according to Takayuki et al (see, for example, English abstract, and in English machine-translation version-pg. 6-8).

Hama et al teach a method for specifically assaying HDL cholesterol in which serum or plasma samples having HDL cholesterol are brought into contact with cholesterol esterase, cholesterol oxidase and bile acid or its salt in the presence of albumin and then the compounds consumed or formed by the reactions between the cholesterol and each of the enzymes are measured. In particular, Hama et al teach that having a nonionic surfactant, albumin and bile acid or its salt at a particular concentration is necessary for reaction to occur with HDL cholesterol specifically (see, for example, English Abstract and pg. 9 of English machine-translation printout).

Takayuki et al and Hama et al do not expressly teach a method wherein the nonionic surfactant is polyoxyethylene alkylamine, polyoxyethylene alkenylamine, or polyoxyethylene polycyclic phenyl ether sulfate.

Miyauchi et al. teach "a method of determining the amount of cholesterol in HDL, which comprises measuring the amount of cholesterol in HDL in a sample in the presence of a sugar compound and/or a protein solubilizing agent" (abstract). They teach the use of cholesterol oxidase and cholesterol esterase in the method as well as the creation and measurement of hydrogen peroxide (col. 5) to determine the amounts of cholesterol present.

They specifically teach "the protein solubilizing agent for determining the amount of HDL cholesterol in the sample, cationic, anionic and nonionic surfactants and a bile acid salt are especially preferable among the surfactants such as compounds (VI), (VII) and (VIII) and the bile acid. Examples of the cationic surfactant include oxyethylene dodecylamine, polyoxyethylene dodecylamine and polyoxyethylene octadecylamine. Examples of the anionic surfactant include sodium cocoylmethyltaurate, sodium lauroylmethyltaurate, sodium myristoylmethyltaurate, sodium palmitoylmethyltaurate and sodium stealoylmethyltaurate. Examples of the nonionic surfactant include polyoxyethylene lauryl ether, polyoxyethylene cetyl ether, polyoxyethylene stearyl ether, polyoxyethylene oleyl ether and polyoxyethylene behenyl ether. Examples of the bile acid salt include sodium cholate, sodium deoxycholate, sodium chenodeoxycholate, sodium ursodeoxycholate, sodium lithocholate, sodium isochenodeoxycholate, sodium 7-oxolithocholate, sodium 12-oxolithocholate, sodium 12-oxochenodeoxycholate and sodium 7-oxodeoxycholate" (col. 4).

Miki et al teach that surfactants for measuring HDL, particularly nonionic surfactants such as polyoxyethylene oleyl ether, in addition to others, preferably those having HLB values of 12 to 17 are useful in reagent solutions which measure HDL cholesterol. They teach that those surfactants can be used alone or in combination (see, for example, col. 5, lines 20-60). Furthermore, they teach that anionic cholic acid or deoxycholic acid may be used in the reagents in addition to the above nonionic surfactants (see, for example, col. 5, lines 30-55).

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the methods disclosed by Takayuki et al, based upon the beneficial teachings provided by Hama et al., Miyauchi et al., and Miki et al. with respect to the

art-recognized method of using bile acids or their salts at particular concentrations in combination with nonionic surfactants, cholesterol esterase, cholesterol oxidase, and albumin to measure HDL cholesterol, for the purpose of specifically reacting the enzymes with HDL cholesterol versus other cholesterol. Also known to one of skill in the art, as evidenced by the prior art, is performing methods of testing for cholesterol components using cholesterol esterase and cholesterol oxidase with cationic surfactants, such as oxyethylene dodecylamine, polyoxyethylene dodecylamine and polyoxyethylene octadecylamine, and nonionic surfactants such as polyoxyethylene lauryl ether, polyoxyethylene cetyl ether, polyoxyethylene stearyl ether, polyoxyethylene oleyl ether and polyoxyethylene behenyl ether, specifically those having HLB values from 12-17, such as polyoxyethylene oleyl ether. Furthermore, Takayuki et al particularly point out that any nonionic surfactant may be used in their methods, while Hama et al teach that using bile acids or their salts would be beneficial to use in combination with the nonionic surfactant and enzymes so as to specifically react with the HDL cholesterol compared to the other cholesterols present in a specimen, and Miyauchi et al. teach that a range of surfactants may be used.

Based upon the teachings provided by Takayuki et al., Hama et al, and the specific teachings provided by Miyauchi et al. and Miki et al., that nonionic surfactants such as polyoxyethylene oleyl ether and others with HLB values between 12 and 17 are useful for specifically reacting with HDL cholesterol, it would have been both obvious and beneficial for the skilled artisan to use the methods taught by Takayuki et al, Hama et al, Miyauchi et al., and Miki et al so as quantify cholesterol in HDL in a sample. From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of

success in producing the claimed invention since one of skill in this art knows the elements of the invention: the enzymes, the reaction, the cationic, anionic and nonionic surfactants are taught by the prior art.

Response to Arguments

Applicant's arguments filed 04 February 2009 have been fully considered but they are not persuasive. Applicants argue that the assay performed with the nonionic detergents in kits A1, A2, B and C were more effective than the detergents of Miki et al., as shown by the lower correlation coefficient of kits a1-a4 (Declaration submitted 05 November 2008) and that one of skill would not have known to choose the more efficient detergents of kits A1, A2, B and C. However, Miyauchi et al. clearly teach that one of skill would know to choose any of the many listed detergents, including those disclosed in the instant kits, and also that the named cationic, anionic and nonionic detergents listed are only examples of the surfactants available to one of skill in this art.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lisa J. Hobbs whose telephone number is 571-272-3373. The examiner can normally be reached on Hotelling - Generally, 9-6 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon P. Weber can be reached on 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Lisa J. Hobbs/
Primary Examiner
Art Unit 1657

ljh